

§ 520.45

21 CFR Ch. I (4–1–04 Edition)

(3) For use only by or on the order of a licensed veterinarian.¹

[40 FR 13838, Mar. 27, 1975, as amended at 67 FR 78355, Dec. 24, 2002]

§ 520.45 Albendazole oral dosage forms.

§ 520.45a Albendazole suspension.

(a)(1) *Specifications.* The product contains 11.36 percent albendazole.

(2) *Sponsor.* See No. 000069 in § 510.600 of this chapter.

(3) *Related tolerances.* See § 556.34 of this chapter.

(4) *Conditions of use in cattle*—(i) *Amount.* 4.54 milligrams per pound of body weight (10 milligrams per kilogram).

(ii) *Indications for use.* For removal and control of the following internal parasites of cattle: Adult liver flukes (*Fasciola hepatica*); heads and segments of tapeworms (*Moniezia benedeni*, *M. expansa*); adult and 4th stage larvae of stomach worms (brown stomach worms including 4th stage inhibited larvae (*Ostertagia ostertagi*), barberpole worm (*Haemonchus contortus*, *H. placei*), small stomach worm (*Trichostrongylus axei*)); adult and 4th stage larvae of intestinal worms (thread-necked intestinal worm (*Nematodirus spathiger*, *N. helvetianus*), small intestinal worm (*Cooperia punctata* and *C. oncophora*)); adult stages of intestinal worms (hookworm (*Bunostomum phlebotomum*), bankrupt worm (*Trichostrongylus colubriformis*), nodular worm (*Oesophagostomum radiatum*)); adult and 4th stage larvae of lungworms (*Dictyocaulus viviparus*).

(iii) *Limitations.* Administer as a single oral dose using dosing gun or dosing syringe. Do not slaughter within 27 days of last treatment. Do not use in female dairy cattle of breeding age: Do not administer to female cattle during first 45 days of pregnancy or for 45 days after removal of bulls. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

(b)(1) *Specifications.* The product contains 4.55 or 11.36 percent albendazole.

(2) *Sponsor.* See No. 000069 in § 510.600(c) of this chapter.

(3) *Related tolerances.* See § 556.34 of this chapter.

(4) *Conditions of use in sheep*—(i) *Amount.* 7.5 milligrams per kilogram of body weight (3.4 milligrams per pound).

(ii) *Indications for use.* For removal and control of the following internal parasites of sheep: Adult liver flukes (*Fasciola hepatica*, *Fascioloides magna*); heads and segments of common tapeworms (*Moniezia expansa*) and fringed tapeworm (*Thysanosoma actinioides*); adult and fourth stage larvae of stomach worms (brown stomach worm (*Ostertagia circumcincta* and *Marshallagia marshalli*), barberpole worm (*Haemonchus contortus*), small stomach worm (*Trichostrongylus axei*)); adult and fourth stage larvae of intestinal worms (thread-necked intestinal worm (*Nematodirus spathiger* and *N. filicollis*), Cooper's worm (*Cooperia oncophora*), bankrupt worm (*Trichostrongylus colubriformis*), nodular worm (*Oesophagostomum columbianum*), and large-mouth bowel worm (*Chabertia ovina*)); adult and larval stages of lungworms (*Dictyocaulus filaria*).

(iii) *Limitations.* Administer as a single oral dose using dosing gun or dosing syringe. Do not slaughter within 7 days of last treatment. Do not administer to ewes during first 30 days of pregnancy or for 30 days after removal of rams. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

[54 FR 25115, June 13, 1989, as amended at 56 FR 50653, Oct. 8, 1991; 59 FR 65711, Dec. 21, 1994; 60 FR 55658, Nov. 2, 1995; 61 FR 4875, Feb. 9, 1996; 64 FR 1504, Jan. 11, 1999]

§ 520.45b Albendazole paste.

(a) *Specifications.* The product contains 30 percent albendazole.

(b) *Sponsor.* See No. 000069 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.34 of this chapter.

(d) *Conditions of use in cattle*—(1) *Amount.* Equivalent to 4.54 milligrams per 1 pound of body weight (10 milligrams per kilogram).

(2) *Indications for use.* For removal and control of the following internal parasites of cattle: adult liver flukes (*Fasciola hepatica*); heads and segments of tapeworms (*Moniezia benedeni*, *M. expansa*); adult and 4th stage larvae of stomach worms (brown stomach worms including 4th stage inhibited larvae